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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,380	07/14/2003	Ty Whitaker	281-398.01	5428

20874 7590 03/22/2007

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EXAMINER	
NASSER, ROBERT L	
ART UNIT	**PAPER NUMBER**
3735	

MAIL DATE	DELIVERY MODE
03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/619,380	WHITAKER ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Robert L. Nasser*. (3)_____.

(2) *Mr. Joseph Milstein*. (4)_____.

Date of Interview: *14 March 2007*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *proposed amendment*.

Identification of prior art discussed: *Harada*.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *discussed the proposed amendment. The examiner indicated Harada was a normal speed and not fast, but that the term fast needed to be defined. Applicant proposed stating faster than a conventional inflation speed. Again, the examiner noted that the term would define over Harada, assuming conventional was defined to be 203 mm hg and any evidence applicant could give on that point would be helpful.*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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FACSIMILE COVER SHEET

Date:	March 12, 2007	Time:	3:00	No. of Pages Transmitted: (Including this Cover Letter)	22
Name		**Company / Location**		**Fax Number**	**Phone Number**
Mr. Nassar (Patent Examiner)		USPTO		571-273-4731	571-272-4731

Comments:

Client/Matter Name	Client/Matter Number	Time Keeper Number

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/619,380	Confirmation No.:	5428
Applicant:	Whitaker et al.	Filed:	July 14, 2003
Art Unit:	3735	Examiner:	Robert L. Nasser
Docket No.:	281-398.01	Customer No.:	44,331

TITLE: MOTION MANAGEMENT IN A FAST BLOOD PRESSURE MEASUREMENT DEVICE

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

In response to the Office Action mailed from the United States Patent and Trademark Office on December 15, 2006, please enter in the above-captioned patent application the Amendments presented herein, and please consider the Remarks that follow. Applicant believes that no fees are due on account of the submission of this paper. However, if Applicant is incorrect and fees in a different amount are due, the Director is hereby authorized to charge any additional fees, or to make any refund of an overpayment, to Deposit Account No. 50-3010.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 10 of this paper.

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Amendment and Response
U.S. Serial No. 10/619,380
Filed: July 14, 2003
Attorney Docket No: 281-398.01

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A blood pressure measurement apparatus, comprising:

an inflatable chamber, said inflatable chamber operable to be inflated during an inflation interval and deflated during a deflation interval;

a sensor coupled to said inflatable chamber, said sensor configured to measure a signal, said signal comprising information indicative of a blood pressure of a vertebrate;

a control module configured to receive as input at least a portion of said signal from said sensor, and to generate as output a control signal having a selected one of a plurality of values responsive to said input;

a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate; and

a second analysis module, said second analysis module selectively operative in response to one of said plurality of values of said control signal, said second analysis module configured to analyze said signal during said deflation interval of said inflatable chamber to extract from said signal said blood pressure of said vertebrate;

whereby said apparatus completes said measurement of said blood pressure of said vertebrate using at least one of said first analysis module and said second analysis module.

2. (Original) The apparatus of claim 1, wherein said deflation interval comprises at least one step deflation interval.

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3. (Original) The apparatus of claim 1, wherein said plurality of control signal values comprises a first value that inhibits operation of said second analysis module and a second value that activates operation of said second analysis module.

4. (Original) The apparatus of claim 1, wherein said blood pressure of said vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

5. (Original) The apparatus of claim 4, further comprising a reporting module configured to report at least one of said systolic blood pressure and said diastolic blood pressure.

6. (Original) The apparatus of claim 1, further comprising a neonate sensor module configured to sense whether said vertebrate is a neonate vertebrate.

7. (Original) The apparatus of claim 6, wherein in response to a positive determination that said vertebrate is a neonate vertebrate, said apparatus completes a blood pressure measurement of said neonate vertebrate using said second analysis module.

8. (Original) The apparatus of claim 7, wherein said signal analyzed by said second analysis module during said deflation interval comprises a signal occurring during at least one step deflation interval.

9. (Original) The apparatus of claim 7, wherein said blood pressure of said neonate vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

10. (Original) The apparatus of claim 9, further comprising a reporting module configured to

report at least one of said systolic blood pressure and said diastolic blood pressure.

11. (Previously Presented) The blood pressure measurement apparatus of claim 1, further comprising:

a motion detection module configured to receive as input at least a portion of said signal from said sensor, said motion detection module configured to detect a secondary motion of said vertebrate distinct from motion associated with said signal comprising information indicative of a blood pressure of a vertebrate and configured to communicate a value to said first analysis module;

whereby, in the event that said value of said secondary motion detected by said detection module is below a predetermined value, said apparatus completes a blood pressure measurement of said vertebrate using said first analysis module.

12. (Original) The apparatus of claim 11, wherein said blood pressure of said vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

13. (Original) The apparatus of claim 12, further comprising a reporting module configured to report at least one of said systolic blood pressure and said diastolic blood pressure.

14. (Original) The apparatus of claim 11, wherein said motion detection module is configured to provide a warning, said warning being generated in response to said secondary motion that exceeds said predetermined value.

15. (Original) The apparatus of claim 14, further comprising an announcement module that announces said warning.

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16. (Original) The apparatus of claim 15, wherein said announcement is a visual announcement.

17. (Original) The apparatus of claim 15, wherein said announcement is an audible announcement.

18. (Original) The apparatus of claim 15, wherein said blood pressure measurement is completed if said secondary motion falls below said predetermined value within a defined time period after said announcement of said warning.

19. (Original) The apparatus of claim 18 wherein said blood pressure of said vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

20. (Original) The apparatus of claim 19, further comprising a reporting module configured to report at least one of said systolic blood pressure and said diastolic blood pressure.

21. (Previously Presented) The apparatus of claim 11, wherein said second analysis module is operative in the event that said value of said secondary motion detected by said motion detector module is at least equal to said predetermined value;

whereby said apparatus completes said measurement of said blood pressure of said vertebrate using said second analysis module.

22. (Original) The apparatus of claim 21, wherein said deflation interval comprises at least one step deflation interval.

23. (Original) The apparatus of claim 21, further comprising a neonate sensor module

configured to sense whether said vertebrate is a neonate vertebrate.

24. (Original) The apparatus of claim 23, wherein in response to a positive determination that said vertebrate is a neonate vertebrate, said apparatus completes said blood pressure measurement of said neonate vertebrate using said second analysis module.

25. (Original) The apparatus of claim 24, wherein said blood pressure of said neonate vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

26. (Original) The apparatus of claim 25, further comprising a reporting module configured to report at least one of said systolic blood pressure and said diastolic blood pressure.

27. (Currently Amended) A blood pressure measurement method, comprising the steps of:

providing an inflatable chamber, said inflatable chamber operable to be inflated during an inflation interval and deflated during a deflation interval;

measuring a signal comprising information indicative of a blood pressure of a vertebrate;

analyzing said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate; and

if necessary, responsive to a control signal, analyzing said signal during said deflation interval of said inflatable chamber to extract from said signal said blood pressure of said vertebrate;

whereby a measurement of said blood pressure of said vertebrate is accomplished.

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28. (Original) The method of claim 27, wherein said deflation interval comprises at least one step deflation interval.

29. (Original) The method of claim 27, wherein said blood pressure of said vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

30. (Original) The method of claim 29, further comprising reporting at least one of said systolic blood pressure and said diastolic blood pressure.

31. (Original) The method of claim 27, further comprising the step of sensing whether said vertebrate is a neonate vertebrate.

32. (Original) The method of claim 31, wherein in response to a positive determination that said vertebrate is a neonate vertebrate, said method completes a blood pressure measurement of said neonate vertebrate by analyzing said signal during said deflation interval.

33. (Original) The method of claim 32, wherein said signal analyzed during said deflation interval comprises a signal occurring during at least one step deflation interval.

34. (Original) The method of claim 32, wherein said blood pressure of said neonate vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

35. (Original) The method of claim 34, further comprising reporting at least one of said systolic blood pressure and said diastolic blood pressure.

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36. (Previously Presented) The blood pressure measurement method of claim 27, further comprising the step of:

detecting a secondary motion of said vertebrate distinct from said motion comprising information indicative of said blood pressure;

whereby, in the event that said secondary motion is below a predetermined value, said method completes said blood pressure measurement.

37. (Original) The method of claim 36, wherein said blood pressure of said vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

38. (Original) The method of claim 37, further comprising reporting at least one of said systolic blood pressure and said diastolic blood pressure.

39. (Original) The method of claim 36, wherein said motion detection module is configured to provide a warning, said warning being generated in response to said secondary motion that exceeds said predetermined value.

40. (Original) The method of claim 39, further comprising an announcement module that announces said warning.

41. (Original) The method of claim 40, wherein said blood pressure measurement is completed if said secondary motion falls below said predetermined value within a defined time period after said announcement of said warning.

42. (Original) The method of claim 41 wherein said blood pressure of said vertebrate

comprises at least one of a systolic blood pressure and a diastolic blood pressure.

43. (Original) The method of claim 42, further comprising reporting at least one of said systolic blood pressure and said diastolic blood pressure.

44. (Original) The method of claim 36, further comprising the steps of:

in the event that said value of said secondary motion detected by said motion detector module is at least equal to said predetermined value, analyzing said signal during said deflation interval of said inflatable chamber to extract from said signal said blood pressure of said vertebrate;

whereby said blood pressure of said vertebrate is determined.

45. (Original) The method of claim 44, wherein said deflation interval comprises at least one step deflation interval.

46. (Original) The method of claim 44, further comprising sensing whether said vertebrate is a neonate vertebrate.

47. (Original) The method of claim 46, wherein in response to a positive determination that said vertebrate is a neonate vertebrate, said method determines said blood pressure of said neonate vertebrate.

48. (Original) The method of claim 47, wherein said blood pressure of said neonate vertebrate comprises at least one of a systolic blood pressure and a diastolic blood pressure.

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49. (Original) The method of claim 48, further comprising reporting at least one of said systolic blood pressure and said diastolic blood pressure.

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Amendment and Response
U.S. Serial No. 10/619,380
Filed: July 14, 2003
Attorney Docket No: 281-398.01

REMARKS

Claims 1-49 were presented.

Claims 6-10, 23-26, 31-35, and 46-49 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Office Action asserts that the specification lacks a disclosure of how to detect whether a patient is a neonate.

Claims 1-5 and 27-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,759,157 to Harada et al. (hereinafter "Harada").

Claims 11-13 and 36-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of U.S. Patent No. 6,405,076 to Taylor et al. (hereinafter "Taylor").

Claims 14-17, 21-22, 39, 40, and 44-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor, and further in view of U.S. Patent No. 4,870,973 to Ueno (hereinafter "Ueno").

Claims 18-20 and 41-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor and Ueno, and further in view of U.S. Patent No. 4,592,365 to Georgi (hereinafter "Georgi").

Independent claims 1 and 27 have been respectively amended to recite in relevant part:

"a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate;"

and

"analyzing said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate."

Support for the amendments is found throughout the Specification as filed, and at least at paragraph [00044] as originally filed, which recites in relevant part:

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> ... The fast cycle comprises inflating the cuff 102 and sensing pressure/volume signals with sensor 106. The sensor electronic module 108 comprises a control module configured to receive as input at least a portion of the signal from the sensor 106, and to generate as output a control signal having a selected one of a plurality of values responsive to said input. As indicated by box 206, a determination is made as regards the extent of motion (or other artifacts) distinct from the expected signal indicative of a blood pressure measurement. A motion detection module configured to receive as input at least a portion of the signal from the sensor performs the determination. Depending at least in part on the magnitude of the control signal, the blood pressure signal is deemed to be suitable for analysis or unsuitable. The signals so sensed are analyzed using a first analysis module. As indicated by box 207, the analyzed information is evaluated to determine of the answer appears to be correct. If the answer appears to be correct, and the blood pressure measurement so arrive at is deemed appropriate, an "answer" or result is obtained, and in some embodiments is enunciated at box 210. ...

Examiner Nasser is thanked for a telephonic interview that took place on March 14, 2007, in which the undersigned participated. The interview discussion covered the rejection of the claims under 35 U.S.C. §102(b), the cited art, and the claims. The Applicant proposed claim language to distinguish the invention over the cited art. There was/was not agreement that the proposed claim language, presented herein as amendments, would distinguish the invention over the cited art. The Examiner indicated that a further search would be required, which search might disclose further material art.

Response to Rejection of Claims 6-10, 23-26, 31-35, and 46-49 under 35 U.S.C. §112, 1st paragraph

Claims 6-10, 23-26, 31-35, and 46-49 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Office Action asserts that the specification lacks a disclosure of how to detect whether a patient is a neonate.

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Amendment and Response
U.S. Serial No. 10/619,380
Filed: July 14, 2003
Attorney Docket No: 281-398.01

Applicants respectfully submit that the Specification as filed contains the following statement at paragraph [00043] of the originally filed application (paragraph [0038] in the application as published as US 2005/0033188 A1):

> The process starts at box 202, labeled "Start," that will be understood to represent all of the steps of initiating operation of the microprocessor-based blood pressure measurement apparatus, including all necessary initial internal testing and diagnostic routines to assure proper operation of the apparatus, as well as operator entry of information needed to identify the subject vertebrate and the circumstances of the measurement. As described hereinbefore, the operator can enter information using any or all of a keyboard, a button, a mouse (in conjunction with a Graphical User Interface (GUI), a menu system, or the like), and/or audible entry of information with a microphone. As required, initialization information can also be downloaded from a database. In order to commence a measurement of the blood pressure of a vertebrate, the operator places the necessary inflatable chamber or cuff on the appropriate location of he vertebrate to be tested, such as an arm of a human being, and confirms that all of the necessary portions of the apparatus are properly made ready. The operator then issues a command to initiate the measurement, such as pressing a button. In one embodiment, at box 204, the apparatus performs an analysis of the signals that it detects to determine whether the subject vertebrate is a neonate. Alternatively, the operator can issue a command indicating that the subject is or is not a neonate.

Applicants clearly described one alternative, namely that an operator informs the apparatus that the subject is a neonate. Applicants also described that information can be downloaded from a database. The Specification include the following statement: An example of a neonate vertebrate is a human having an age of 28 days or less since birth. If the database includes such normal information as a date of birth, and the apparatus uses such conventional information as the current date and time in reporting test results, it would be a straightforward matter for the apparatus to determine whether a particular subject was younger or older than 28 days. This is a second way in which the apparatus can determine if the subject is a neonate. A third way that an apparatus can determine if a subject is a neonate involves well-known technology, namely identifying a size of a blood pressure cuff used to measure the blood

pressure of the subject. U.S. Patent No. 5,022,403, issued on June 11, 1991 to LaViola and assigned to CAS Medical Systems, Inc., describes an apparatus for measuring blood pressure that distinguishes between an adult blood pressure cuff and a pediatric blood pressure cuff. The Abstract teaches:

> ... For example, the device can employ an adult cuff, or a pediatric cuff. To accomodate the different cuff sizes, the device has more than one bleed orifice with which it controls the deflation steps. The onboard computer is programmed to use a selected one of the bleed orifices in the first bleed step and to use the time duration of the first bleed step to determine what size cuff is being used. Once the cuff size is determined, the proper bleed orifice designed for the determined cuff size is made operative, and the testing continues. ...

Applicants have also found, using the web archives available through www.archive.org, that the web site of CAS Medical Systems, Inc. (www.casmed.com) as early as April 14, 2000 included neonatal products, including a neonate blood pressure cuff referred to as a Pedisphyg Blood Pressure Cuff. The web page states: "sizes available to fit any infant." Copies of the relevant pages are appended hereto for the convenience of the Examiner.

Applicants respectfully submit that they have explicitly explained at least one way, and possibly two ways, that the apparatus can determine if a subject is a neonate, and that additionally, such a determination is well-known in the patent literature. for example by determining whether a blood pressure cuff of a size suitable for a neonate is being used. Applicants further make note of MPEP 2164.01, which states in relevant part: "A patent need not teach, and preferably omits, what is well known in the art."

Response to Rejection of Claims 1-5 and 27-30 under 35 U.S.C. §102(b)

Claims 1-5 and 27-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Harada. Presently amended independent claims 1 and 27 are the only independent claims pending in the application.

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As is explained in U.S. Patent No. 4,860,759, the entire disclosure of which was incorporated by reference into the present application, a common rate of deflation of a blood pressure cuff during a measurement is 3 millimeters of mercury (3 mm of Hg) per second. Conventionally, if blood pressure is being measured during an increase of pressure in the cuff, the same 3 mm of Hg per second rate of change is used. By comparison, in the present invention, in which "fast" inflation and deflation rates are used, the fast rate is at least 5 mm of Hg per second, and can be 10 mm of Hg per second.

Harada teaches a method of measuring blood pressure. Harada teaches that the blood pressure measurements are performed during either a slow inflation period and a slow deflation period of the blood pressure cuff (see Fig. 4 of Harada; see steps SA3 and SA10 of Figs. 3 and 6 of Harada). Harada teaches at column 5, lines 43-48, that

> At Step SA3, the pressure regulating valve 14 is switched to a slow-inflation position in which the pressure regulating valve 14 permits the pressurized air to be supplied to the cuff 10 at a rate suitable for blood pressure measurements, for example, 2 to 3 mmHg/sec, as shown at point t_2 in FIG. 4

Harada teaches at column 6, lines 24-29, that

> At Step SA10, the pressure regulating valve 14 is switched to a slow-deflation position in which the cuff pressure P_c is slowly decreased at a rate suitable for blood pressure measurements, for example, 2 to 3 mmHg/sec, as indicated at broken line in FIG. 4.

,Applicants respectfully submit that Harada does not teach or suggest "a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate;" or the corresponding analysis step.

Because Harada fails to teach or suggest either a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said

vertebrate or the corresponding analysis step, Harada fails to anticipate independent claims 1 and 27 as presently amended. Applicants respectfully submit that independent claims 1 and 27 are patentable over Harada. Applicants further submit that claims 2-26 which depend from independent claim 1, and claims 28-49 which depend from independent claim 27 are patentable as depending from allowable base claims.

Response to Rejection of Claims 11-13 and 36-38 under 35 U.S.C. §103(a)

Claims 11-13 and 36-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor.

Taylor teaches methods of filtering blood pressure measurement signals to remove artifacts.

At column 5, lines 1-12, Taylor teaches:

> Also as is known to those skilled in the art, apparatus 10 is usable to measure a subject's blood pressure and heart rate during a suitable measurement cycle. For practicing the present invention, the usual NIBP-cycle may be used as a measurement cycle in the practice of the present invention. Such cycle includes monitoring and processing pressure-signal information from cuff 16 for a defined range of pulsatile information, i.e. from a supra-systolic pressure (cuff inflated) to below diastolic pressure (cuff deflated preferably gradually). Gradual cuff deflation is preferred because it optimizes patient comfort and promotes accuracy of data measurement because, in stepwise cuff deflation, data occuring during step deflation can be lost.

At column 5, lines 61-67, Taylor teaches:

> As used herein, filtering of data means to take an input signal carrying data, and perform preselected mathematical operations on that data to produce filtered data. The specific type of filtering presently contemplated by the invention involves removing noise (also referred to as artifact) from the data. The filtering of the PRESSURE/ECG data can be done using any suitable filter.

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At column 8, lines 36 to 42, Taylor teaches that

> Signal noise is estimated by comparing the real-time incoming signal with the composite signal averaged pulse. When noise is low the bleed rate can be set to the highest rate. With increasing noise, a slower bleed rate and a lower corner frequency filter is used. In extremely severe noise, the cuff pressure is held constant and signal ignored for up to ten seconds.

Taylor does not teach or suggest making a "a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate;" or the corresponding analysis step.

Because Taylor fails to teach or suggest either a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate or the corresponding analysis step, the combination of Taylor with Harada (assuming *arguendo* that such combination is shown to be motivated) fails to anticipate independent claims 1 and 27 as presently amended. Applicants reserve the right to argue that no motivation has been shown to combine Taylor with Harada. Applicants respectfully submit that independent claims 1 and 27 are patentable over the combination of Taylor with Harada. Applicants further submit that claims 11-13 which depend from independent claim 1, and claims 36-38 which depend from independent claim 27 are patentable as depending from allowable base claims.

In addition Applicants note for the record that the Examiner has a burden of demonstrating that there exists a motivation, suggestion, or teaching to combine the teachings of two or more patents, which motivation, suggestion, or teaching must be found independent from the teachings of the application being examined. See *In re Werner Kotzab*, 217 F.3d 1365 (CAFC, 2000).

The CAFC stated in *Kotzab* at pages 1369-70 (citations omitted):

> Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However,

identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.

The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. Broad conclusory statements standing alone are not "evidence."

Response to Rejection of Claims 14-17, 21-22, 39, 40, and 44-45 under 35 U.S.C. §103(a)

Claims 14-17, 21-22, 39, 40, and 44-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor, and further in view of Ueno.

Ueno teaches systems and methods of detecting artifacts in blood pressure measurements made with a meter. However, Ueno fails to teach or suggest a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate or the corresponding analysis step.

Accordingly, combining Ueno with Taylor and Harada (assuming *arguendo* that such combination is shown to be motivated) fails to anticipate independent claims 1 and 27 as presently amended. Applicants reserve the right to argue that no motivation has been shown to combine Ueno with Taylor and with Harada. Applicants respectfully submit that independent

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claims 1 and 27 are patentable over the combination of Ueno, Taylor and Harada. Applicants further submit that claims 14-17, and 21-22 which depend from independent claim 1, and claims 39, 40, and 44-45 which depend from independent claim 27 are patentable as depending from allowable base claims.

Response to Rejection of Claims 18-20 and 41-43 under 35 U.S.C. §103(a)

Claims 18-20 and 41-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor and Ueno, and further in view of Georgi.

Georgi teaches systems and methods of making blood pressure measurements made with an electronic meter. However, Georgi only teaches or suggests making the measurement during the deflation portion of an inflation-deflation cycle. Georgi teaches at column 23, lines 25 to 31 that:

> The measuring of blood pressure, in accordance with the present invention, is accomplished during a measurement cycle which consists of three basic segments:
>
> (1) The pump-up phase,
>
> (2) The deflation and data collection phase, and
>
> (3) The data analysis and computation of blood pressure and pulse rate phase.

Therefore, Georgi fails to teach or suggest a first analysis module, said first analysis module configured to analyze said signal during a fast inflation of said inflatable chamber before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate or the corresponding analysis step.

Accordingly, combining Georgi with Ueno, with Taylor, and with Harada (assuming *arguendo* that such combination is shown to be motivated) fails to anticipate independent claims 1 and 27 as presently amended. Applicants reserve the right to argue that no motivation has been shown to combine Georgi withUeno, with Taylor, and with Harada. Applicants respectfully

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submit that independent claims 1 and 27 are patentable over the combination of Georgi, Ueno, Taylor and Harada. Applicants further submit that claims 18-20 which depend from independent claim 1, and claims 41-43 which depend from independent claim 27 are patentable as depending from allowable base claims.

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Amendment and Response
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CONCLUSION

Claims 1-49 are pending in the application.

For the reasons given above, Applicants respectfully request that the application be reconsidered and that the rejections of Claims 1-49 be withdrawn. Applicants submit that Claims 1-49 are now in proper condition for allowance, and requests the issuance of a Notice of Allowance at the Examiner's earliest convenience.

If the Examiner believes that contact with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is requested to call Applicants' attorney at the phone number noted below.

Respectfully submitted,
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